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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,066	10/18/2001	Frederick M. Ausubel	00786/387003	3890
21559	7590	05/18/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			PARAS JR, PETER	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 05/18/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,066

Applicant(s)

AUSUBEL ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) 23-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0204.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's amendment received on 2/27/04 has been entered. Claims 1-86 are pending. Claims 1-11 are under current consideration.

Election/Restrictions

Claims 12-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response received on 5/27/03.

This application contains claims (12-86) drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

The amendment to specification placing the priority statement in the first line of the specification has been entered. Priority of the instant application has been perfected.

Oath/Declaration

The substitute declaration received on 2/27/04 has been entered.

Drawings

The substitute drawings received on 2/27/04 have been approved.

Specification

The previous objection to the specification has been withdrawn as the hyperlinks have been removed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under are 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The previous rejection is maintained for the reasons of record advanced on pages 4-7 of the Office action mailed on 8/20/03.

Applicant's arguments filed 2/27/04 have been fully considered but they are not persuasive. Applicants assert the Examiner has failed to meet the initial burden of challenging Applicant's assertion of utility. Applicants argue the asserted utilities of identifying a nematode having enhanced susceptibility to a pathogen are (1) to identify gene targets for the treatment of pathogen-associated disease and (2) to identify a compound that modulates a host resistance as a treatment for a pathogen-associated disease. Applicants further assert the invention facilitates the identification of novel targets and therapeutic approaches for preparing therapeutic agents active on host factors and genes that enable a host to mount its defense against pathogen invasion and infection. Applicants further assert the claimed methods provide a simple means for identifying host factors and genes that enable a host to combat pathogen infection

and compounds capable of either inhibiting pathogenicity or enhancing a host's resistance capabilities to such pathogens. See pages 7-8.

In response, the Examiner asserts the specification has not correlated the nematodes identified by the claimed methods with any disease. Merely asserting that nematodes identified by the claimed methods can be used to screen for potential therapeutic agents is not sufficient. The evidence of record has not provided a correlation between an identified nematode and a disease. Therefore, it is not understood which disease may be treated by any compound identified using the nematodes. It is noted the claims are broadly directed to any mutagenized nematode, presumably comprising a mutation in any gene with no correlation made by the evidence of record between a mutated gene and a disease. See pages 4-5 of the Office action mailed on 8/20/03. The asserted utility of using the nematode for identifying new genes or factors that allow a host to combat infection is an invitation for further research by the skilled artisan. In Brenner, the Court held that materials to be used as an object of research or methods of using those materials as an object for research have raised issues as to whether those materials possess a real world context of use of substantial utility. See Brenner v. Manson, 148 USPQ 689 (US SupCt 1966). The method producing a product, which lacks utility, also lack utility.

Applicants argue that the well-established utility of the claimed invention is readily apparent to one skilled in the art given the strong connection between the nematode experimental model system and pathogenesis of disease found in man.

Applicants point out that three recent Nobel prize winners pioneered research in *C. elegans*. See pages 9-10

In response, the Examiner acknowledges the pioneering research in *C. elegans* by the Nobel prize winners. However, the relevance of such to the present invention is not clear as such research was not related to the instant invention.

Applicants point out that Garrington as relied upon by the Examiner for the proposition that biochemical diversity exists among MAPK pathway members, and diversity renders difficult the correlation between nematode and mammalian disease or pathogens. Applicants argue that Garrington accepts MAPK components identified in *C. elegans* as having mammalian counterparts. See pages 10-11.

In response, the Examiner maintains the specification has failed to provide evidence of a correlation between nematode and mammalian diseases or pathogens as they relate to the MAPK signal transduction pathway. The evidence of record has failed to correlate the nematode and mammalian MAPK pathway components. The evidence of record has also failed to correlate a mutated *C. elegans* MAPK component with any mammalian disease state. See page 6 of the previous Office action. It is maintained the MAPK pathway is comprised of many biochemically diverse members as evidenced by Garrington. See pages 6-7 of the previous Office action. However, neither the specification nor any art of record has taught what component of the MAPK pathway when mutated in a nematode correlates to a mammalian disease state leaving the skilled artisan to speculate and investigate the uses of the claimed methods and nematodes identified therefrom. The specification essentially gives an invitation to

experiment wherein the artisan is invited to elaborate a functional use for the claimed methods and nematodes identified therefrom.

Accordingly, the previous rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The previous rejection is maintained as set forth on page 7 of the previous Office action and above.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

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**PETER PARAS, JR.
PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read "Pete Paras", written in a cursive style.